DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

October 5, 2004

Warning Letter No. 2005-NOL-01

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Donald W. Shockney, President
Adelines Wholesale, Inc.
1455 Lebanon Road
Nashville, Tennessee 37217

Dear Mr. Shockney:

On August 19-20, 2004, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 1455 Lebanon Pike, Nashville, TN. During the inspection, copies of your labeling were collected. Review of your labels revealed your firm's sandwiches are not labeled in compliance with Title 21 of the *Code of Federal Regulations* (21 CFR), Part 101, Food Labeling, which causes your sandwiches to be misbranded within the meaning of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the CFR through links in FDA's home page at http://www.fda.gov.

Our review of your labels revealed the following:

- Your sandwiches are misbranded within the meaning of Section **403(i)(2)** of the Act because the labels do not declare the components of the ingredients, which consist of two or more ingredients, as required by **21 CFR 101.4(b)(2)**. For example, the components of the "bread" ingredient, when declared as such, must include a parenthetical listing of the ingredients comprising each specific type of bread.

- Your sausage and biscuit, and egg, sausage, and biscuit sandwiches are misbranded within the meaning of Sections **403(a)** and **403(k)** of the Act because the sandwiches contain the chemical preservative, sorbic acid, but it is not declared on the label. The presence of chemical preservatives and a description of the function of the preservatives must be declared on the label to comply with **21 CFR 101.22(j)**.

- Your sandwiches with sausage are misbranded within the meaning of Section **403(i)(2)** of the Act because the sausage contains monosodium glutamate, which is not declared by its common and usual name "monosodium glutamate," as required by **21 CFR 101.22(h)(5)**.

- Your ham and swiss sandwiches, and chicken cheese sandwiches, both on poppy bun, are misbranded within the meaning of Section **403(i)(2)** of the Act because the poppy bun contains FD&C Yellow #5 and FD&C Yellow #6, which are not declared on the label by specific name, as required in the list of ingredients by **21 CFR 101.22(k)(1)**.

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. It is your responsibility to assure all of your products are labeled in compliance with all applicable statutes and regulations enforced by FDA.

You should take prompt action to correct the violations. Failure to promptly correct violations may result in regulatory action without further notice, including seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to bring your firm into compliance with the law. Your response should include each step taken to correct the violations and prevent their recurrence. If you cannot complete all corrections within 15 working days, explain the reason for your delay and state when any remaining deviations will be corrected. Please include copies of any labeling demonstrating corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Kimberly L. McMillan, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217. If you have any questions concerning the violations noted, please contact Ms. McMillan at (615) 781-5380 extension 138.

Sincerely,

H. Tyler Thornburg
Director, New Orleans District

Enclosures:
-21 CFR 101.4
-21 CFR 101.22